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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,806	01/22/2004	Yuichi Kataishi	NPR-132	2300

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,806	KATAISHI ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,7,11,13,15,17,19,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7,11,13,15,17,19,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/27/2006 has been entered.

Acknowledgments

2. This office action is in response to the reply filed on 7/27/2006.

3. In the reply, claim 1 has been amended. Claims 1, 3, 5, 7, 11, 13, 15, 17, 19, 21, and 22 are pending.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second concave cut surface extending from the ledge surface and angled in the proximal direction of the catheter must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner whether claim 1 recites one or two concave cut surfaces. The description in the specification and the Figures of the Applicant's invention show a single concave cut surface; however, claim 1 recites "at least one portion of the cut surface on the proximal side of the cut surface being concave in the angled direction" on lns 13-15 and then goes on and additionally recites "a second concave cut surface extending from the ledge surface and angled in the

proximal direction of the catheter" on lns 21-23. Appropriate clarification and correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Martin (4451252). Martin discloses a thrombus suction catheter comprising a tube having a lumen passing through from a proximal end to a distal end (Fig 1, 8; col 1; wherein the Examiner notes that the catheter is fully capable of suctioning thrombus); a distal end opening having an angled cut surface (40a, 34a; Fig 8); at least a part on the proximal end side of the cut surface being formed in a concave shape in the angled direction (40a); and the distal end side of the cut surface being formed to be flat and flexible in the distal end opening (section of 34a; distal to 40a merging into 34a shown in Fig 8).

9. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Bridgeman (3955579). Bridgeman discloses a thrombus suction catheter comprising a tube having a lumen passing through from a proximal end to a distal end (Fig 2; Summary); a distal end opening having an angled cut surface (20); at least a part on the proximal end side of the cut surface being formed in a concave shape in the angled direction (proximal portion of 30; Fig 2); and the distal end side of the cut surface being formed to be flat

and flexible in the distal end opening (flat section of 30; Fig 2); a first cut surface angled in the proximal direction of the catheter (7; Fig 3), a ledge surface parallel to the longitudinal axis of the catheter (14; Fig 3) extending from the first cut surface in the proximal direction to a second cut surface that is concave and angled in the proximal direction of the catheter (16; Figs 3, 4)

10. Claims 1, 3, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Takase (5084013). In reference to claims 1 and 3, Takase discloses a flexible plastic tube with a first lumen from the proximal to distal end (Fig 2a-b and related text; Summary), an insertion port in the catheter apart from the distal end of the catheter (Figs 2a-b), a second lumen extending from the insertion port to an opening at the distal end (5; 5a), a distal end opening having a cut surface angled with respect to the axis of the catheter (2a), the cut surface ending in a necked-down tip including the second lumen for the guidewire at a distal side of the cut surface (Fig 2a,b), the cut surface having a first cut surface extending from a proximal side of the necked-down tip and angled in the proximal direction of the catheter (distal portion of 2a (ie closest portion of 2a to 3a in Fig 2b), a ledge surface which is substantially parallel to the longitudinal axis of the catheter and extends from the first cut surface in the proximal direction (flat portion of 2a; Fig 2b) and a second concave cut surface extending from the ledge surface and angled in the proximal direction of the catheter (proximal portion of 2a; Fig 2b); the necked-down tip being eccentric to the longitudinal axis (Fig 2a-b).

11. In reference to claim 22, Takase discloses a thrombus suction catheter comprising a tube having a lumen passing through from a proximal end to a distal end

(Fig 2a-b); a distal end opening having an angled cut surface (2a); at least a part on the proximal end side of the cut surface being formed in a concave shape in the angled direction (proximal concave surface of 2a shown in Fig 2b); and the distal end side of the cut surface being formed to be flat and flexible in the distal end opening (flat portion of 2a distal to the concave surface discussed above shown in Fig 2b).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1, 3, 5, 7, 11, 13, 15, 17, 19, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al (6152909) in view of Windischman et al (2716983).

14. In reference to claims 1, 3, 7, 15, 17, 19, 21, and 22 Bagaoisan et al discloses an aspiration catheter (210) with a tube with a lumen from the proximal to distal end (214), an insertion port in the catheter apart from the distal end of the catheter (211), a second lumen extending from the insertion port to an opening at the distal end (212), a third lumen (Fig 14) have a reinforcing wire (216a or 216b) that ends at a position apart from the distal end of the catheter (col 11, lns 18-21), a distal end opening having a cut surface angled with respect to the axis of the catheter (212; Fig 13) ending in a surface that is flat and flexible (Fig 13; col 11, lns 43-47) on the necked-down tip at the distal side of the cut surface (Fig 13), the necked-down tip having a second lumen (214) and

being eccentric to the longitudinal axis (Fig 13, 14), having a marker (224) for identifying the position of the distal tip in the body, the aspiration pump can provide aspiration pressure in variable and continuous settings at the proximal end of the catheter (col 12; lns 64-66), and the aspiration pump can exceed a suction pressure of 650 mmHg (12.5 psi) while preferably not exceeding 30 psi (col 16, lns 10-15).

15. However, Bagaoisan et al does not disclose a portion of the cut surface on the proximal side being concave in the angled direction. Windischman et al teaches that it is known to have a first cut surface angled in the proximal direction of the catheter (7; Fig 3), a ledge surface parallel to the longitudinal axis of the catheter (14; Fig 3) extending from the first cut surface in the proximal direction to a second cut surface that is concave and angled in the proximal direction of the catheter (16; Figs 3, 4) for the purpose of providing a distal end opening structure to the lumen that helps prevent the lumen from becoming clogged. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal end opening cut surface as taught by Bagaoisan et al with the cut surfaces as taught by Windischman et al for the purpose of providing a distal end opening structure to the lumen that helps prevent the suction lumen from becoming clogged.

16. In reference to claim 5, Bagaoisan et al and Windischman et al disclose the invention substantially as claimed except for expressly disclosing that the opening at the distal end of the catheter provides a pressure loss at the start of suction of 90% or less. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a pressure loss at the start of

suction of 90% or less because the Applicant has not disclosed that having a pressure loss at the start of suction of 90% or less provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the pressure loss response of the catheter of Bagaoisan et al and Windischman et al because the aspiration catheter performs the same purpose of removing thrombi from blood vessels through similar sized lumens and a similar suction source. Therefore, it would have been an obvious matter of design choice to modify Bagaoisan et al and Windischman et al to obtain the invention as specified in claim 5.

17. In reference to claims 11 and 13, Bagaoisan et al and Windischman et al disclose the invention substantially as claimed except for expressly disclosing that the insertion port is provided at a position 25-35 cm from the distal end of the opening of the distal end of the catheter. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the insertion port at a position 25-35 cm from the distal end of the catheter because the Applicant has not disclosed that having the insertion port at a position 25-35 cm from the distal end of the catheter provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the insertion port of Bagaoisan et al and Windischman et al because the insertion port and guidewire lumen has the same purpose of maneuvering the catheter in the body. Therefore, it would

have been an obvious matter of design choice to modify Bagaoisan et al and Windischman et al to obtain the invention as specified in claims 11 and 13.

Response to Arguments

18. Applicant's arguments filed 7/27/2006 have been fully considered but they are not persuasive.

19. The Applicant argues that the rejection of claims 1, 3, 5, 7, 11, 13, 15, 17, 19, 21, and 22 under 35 U.S.C. 103(a) as being unpatentable is improper because:

i. Regarding Windischman, the Examiner's dictionary use of the term "catheter" is not proper because in the medical arts, a combination of a tube and a guidewire is terms a "catheter." (Remarks, pg 10, paragraph 2)

ii. Windischman does not disclose the purpose of providing a distal end opening structure to the lumen that helps the lumen from becoming clogged by a suctioned thrombus as the Examiner cited. (Remarks, pg 11, paragraph 1)

iii. Windischman has a first cut surface that is sharply beveled at an angle of approx. 12 degrees providing a sharpened tip for the purpose of piercing the diaphragm or skin, which would not be desireable since the beveled tip would pierce the patient's vasculature and cause trauma. (Remarks, pg 11, paragraph 2)

20. In response to applicant's argument (i) the Examiner notes that one of ordinary skill in the art at the time the invention was made giving the broadest reasonable interpretation in the medical arts of a claim recitation of "catheter" does not rule out all

interpretations except a combination of a tube and a guidewire. The Webster's dictionary definition of catheter gives a reasonably broad interpretation of the definition of a catheter in the medical arts except in cases where the Applicant has explicitly provided a definition of a catheter. Furthermore, the Examiner notes that many catheters do not necessitate guidewires and are not combinations of a tube and a guidewire.

21. In response to applicant's argument (ii) it is elementary that the mere recitation of a newly discovered function of property, inherently possessed by things in the prior art, does not cause a claim drawn to distinguish over the prior art. Additionally, where the Examiner has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in prior art does not possess the characteristic relied on. See *In re Swinehart,* 169 USPQ 226 (CCPA 1971). In the instant case, the disclose of Windischman explicitly states that the design of the piercing needle end, or catheter end, is designed for the purpose of providing a distal end opening structure to the lumen that helps prevent the lumen from becoming clogged to permit fluid flow there through (col 1, lns 15-17). The distal end opening of the catheter of Bagaoisan has fluid flow there through; hence, the design of the piercing needle end, or catheter end, that helps provide a distal end opening structure to the lumen from becoming clogged and allowing fluid flow there through is in the same problem solving area motivation to modifying the distal end opening of Bagaoisan with the piercing needle end design

exists to provide a distal end opening structure to the lumen that helps prevent the lumen from becoming clogged. It is functionally inherent that the distal end structure of Windischman will inherently prevent the lumen from being clogged by a suctioned thrombus.

22. In response to applicant's argument (iii) the Examiner notes that the sharply beveled first cut surface of Windischman will end into the second lumen and not for a sharp tip (see Fig 13). Therefore, because a sharp tip will not be formed and the second lumen will extend distally of the first cut surface one of ordinary skill in the art at the time the invention was made would not expect the 12 degree angled bevel to pose a trauma threat to a patient's vasculature.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER